REMARKS/ARGUMENTS

The present communication responds to the Office Action of July 9, 2003. In that Office Action, the Examiner rejected claims 11-15 and 23-27 under 35 U.S.C. §102(b), claims 11 and 16 under 35 U.S.C. §102(e), and claims 17-19 under 35 U.S.C. §103(a). The Examiner did not address claims 20-22.

In this paper, for clarification purposes, claims 11-27 have been cancelled without prejudice and claims 28-75 have been added. New claims 28-45 correspond generally with cancelled claims 11-22, new claims 46-60 correspond generally with cancelled claims 23-27, and new claims 61-75 incorporate limitations from both sets of previous claims. The drawings have been amended to renumber the profile and cross-sectional views of Figure 1 as Figures 1, 2, and 3 and to renumber the profile and cross-sectional views of Figure 2 as Figures 4, 5, 6, 7, and 8. Figures 1 and 4, formerly Figures 1 and 2, have further been amended to label the cross-sections of new Figures 2, 3, 5, 6, 7, and 8. Amendments have been made to the specification such that the specification corresponds to the new figure numbering. Further amendments have been made to the specification regarding formalities. No new matter has been added through these amendments.

Rejection Under 35 U.S.C. §102

Claims 11-15 and 23-25 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 4,694,832 to Ungerstedt. Ungerstedt discloses a dialysis probe comprising a dialysis membrane and ducts for flow of the perfusion fluid over the membrane. (Col. 4, lines 48-50). The membrane is surrounded by a tubular mounting 2 consisting of a thin-walled metal sleeve of such shape and inner diameter that the membrane 1 can be inserted therein. (Col. 4, lines 59-61, Col. 4, lines 67 – Col. 5, line 2). The dialysis membrane 1 is inserted in its entirety in the mounting 2, the wall of which has an opening 3 in which a portion of the membrane surface is exposed. Two ducts 11, 12, shaped as thin-walled metal tubes, are provided for perfusion fluid flow. The two ducts 11, 12 have a diameter so that they fit inside the probe, one duct 11 having its opening located in the vicinity of the distal end of the portion of the membrane 1 exposed by the mounting, while the other duct 12 has its opening inside the probe located in the vicinity of the proximal end of said membrane portion. The longer of the two ducts 11, 12 is intended for introduction of the perfusion fluid, while the shorter duct is intended for drawing off the fluid.

(Col. 5, line 57 – Col. 6, line 11). Substantially all of the inner surface of the membrane opposite the outer exposed surface of the membrane is exposed to the flow of liquid between the ducts 11 and 12. (Col. 6, lines 44-54).

Ungerstedt does not disclose or suggest a micro-dialysis probe having a supply line and a drainage line together forming a probe shaft and being arranged as separate hollow channels of the probe shaft and having a dialysis section formed generally therebetween, the drip-feed solution experiencing an inversion in the area of the dialysis section, as specifically recited in claim 28, which generally corresponds with cancelled claim 11. Ungerstedt further does not disclose or suggest a micro-dialysis probe having a hollow fiber forming a supply line and a drainage line, the micro-dialysis probe including a supporting profile inserted into the hollow fiber that separates the supply line from the drainage line, as specifically recited in claim 46, which generally corresponds to cancelled claim 23. Thus, the rejection of the claims as anticipated by Ungerstedt should be withdrawn.

Claims 11 and 16 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,264,627 to Liska et al. Liska et al. discloses a catheter for insertion into a blood vessel. The catheter body 2 includes two longitudinal channels 23, 24 designed for circulating dialysis solution, and at their proximal ends, are connected to means 10 for circulating, monitoring, or analyzing, and preferably collecting the dialysis solution. (Col. 3, lines 9-14). At a distance from its distal end, an opening in the catheter body 2 is formed by cutting away a portion of the catheter body 2 in the wall region of channel 23, whereby a section of channel 23 is opened, and a chamber 26 is formed. The chamber 2 is a microdialysis chamber and has a wall formed by a microdialysis membrane 30. (Col. 3, lines 27-34). Channels 23 and 24 are connected by an opening 27 between the chamber 26 and channel 24, so that the dialysis solution can flow between the channels. (Col. 3, lines 40-44). In a region around the opening 25, the catheter body 2 is provided with microdialysis membrane 30 having a socket-like shape, and surrounding a portion of the catheter body 2. (Col. 3, lines 53-55).

Liska et al. does not disclose or suggest a micro-dialysis probe having a supply line and a drainage line, together forming a probe shaft, the drainage line being formed as a hollow fiber, with a dialysis section formed therebetween, the drip-feed solution experiencing an inversion in the area of the dialysis section, and wherein the probe includes a distal probe tip for introducing the probe into subcutaneous tissue, as specifically recited in claim 28, which generally

corresponds with cancelled claim 11. Thus, the rejection of the claims as anticipated by Liksa et al. should be withdrawn.

Claims 26-27 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,441,481 to Mishra et al. Mishra et al. discloses a microdialysis probe having a lumen means for mounting a primary probe to it, a dialysis chamber, an inlet passageway to the chamber and an outlet passageway from the chamber. (Col. 3, lines 38-44). The probe 20 comprises an elongated central tube 22 arranged to receive in its central passageway a primary probe 24, such as an indwelling catheter, a biopsy needle, or an intercranial pressure monitor to have access to the internal site at which the microdialysis probe 20 will be located. (Col. 4, lines 57-63). An annular dialysis chamber 26 is mounted on the distal end of the central tube 22. A fluid inlet tube 28 and a fluid outlet tube 30 communicate with the interior 32 of the dialysis chamber. A cylindrical outer wall 34 extends concentrically about and somewhat close to the outer periphery of the distal end of the central tube 22 to form the dialysis chamber therebetween. (Col. 5, lines 1-11). The inlet tube's open end 28A is located within and adjacent the bottom or distal end 38 of the dialysis chamber. (Col. 5, lines 21-25). The open end 30A of the outlet tube is located within the dialysis chamber adjacent the top or proximal end 40 thereof. (Col. 5, lines 28-31). The distal end 28A of the entry tube 28 and the distal end 30A of the exit tube 30 are situated farthest from each other to allow a maximum circulation of the fluid within the chamber 32. (Col. 6, lines 7-11). The central tube's lumen 22 serves as a passage for the releasable mounting of a primary invasive device. (Col. 6, lines 30-33). The inlet and outlet tubes 28 and 30 extend along and are secured to the outer surface of the central tube 22. (Col. 7, lines 4-6).

Mishra et al. does not disclose or suggest a micro-dialysis probe having a hollow fiber forming a supply line and a drainage line, the supply line and the drainage line being arranged as separate hollow channels of the probe shaft and together being formed by the shaft itself, the supply line and the drainage line extending substantially side-by-side, as specifically claimed by claim 46, which corresponds generally to cancelled claim 23, from which claims 26 and 27 depended. Thus, rejection of the claims as anticipated by Mishra et al. should be withdrawn.

Rejection under 35 U.S.C. §103

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,264,627 to Liska et al. in view of U.S. Patent 4,694,832 to Ungerstedt.

Claims 18-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,264,627 to Liska et al. in view of U.S. Patent 5,257,977 to Eshel. Specifically, the Examiner asserted that Liska teaches all the claimed subject matter except for the profile having a star or flat shape, that Eshel teaches the common profile shapes of star and flat shapes, and that it would have been obvious to one of ordinary skill in the art that the lumens of Liska could just as effectively been designed with a partition dividing up a larger lumen such as that taught by Eshel, as it was with lumens developed in a solid substrate. The Examiner concluded that both of these configurations are well-known and are interchangeable in the art of catheters.

As discussed above, neither Liska et al. nor Ungerstedt, alone or in combination, disclose or suggest each of the elements of the present invention, as claimed. The combination of Eshel and Liska et al. also fails to disclose or suggest a micro-dialysis probe having a supply line and a drainage line, together forming a probe shaft, the drainage line being formed as a hollow fiber, with a dialysis section formed between the supply line and the drainage line, the drip-feed solution experiencing an inversion in the area of the dialysis section and wherein the probe includes a distal probe tip for introducing the probe into subcutaneous tissue, as specifically recited in claim 28, which corresponds generally to cancelled claim 11, from which claims 18 and 19 depended. Thus, rejection of the claims as being unpatentable over Liska et al. in view of Eshel or over Liska et al. in view of Ungerstedt should be withdrawn.

Conclusion

None of the cited references discloses a micro-dialysis probe having a supply line and a drainage line, the drainage line formed as a hollow fiber, the supply line and the drainage line together forming a probe shaft and having a dialysis section formed therebetween wherein the drip-feed solution experiences an inversion in the area of the dialysis section, as specifically recited in claim 28. None discloses a micro-dialysis probe having a hollow fiber forming a supply line and a drainage line, the supply line and the drainage line extending substantially side-by-side, and a supporting profile being inserted into the hollow fiber and separating the supply line from the drainage line, as specifically recited claim 46. None discloses a microdialysis probe having a supply line and a drainage line, a dialysis section being formed therebetween wherein the drip-feed solution experiences an inversion in the area of the dialysis section, as specifically recited in claim 61.

Each of the remaining claims depends either directly or indirectly from claims 28, 46, and 61 and are allowable for the same reasons, further in view of their additional restrictions.

An additional twenty-eight (28) claims have been generated by this paper, and a check in the amount of $504.00 is enclosed to cover the fees. A Petition to extend the time to respond by three months (from October 9, 2003 to January 9, 2004) is enclosed herewith, along with a check in the amount of $950.00. The Office is also hereby authorized to charge any deficiency associated with this paper or the Petition to Deposit Account No 04-1420.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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